Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

PD

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO
09/368,670	08/05/99	LLINAS-BRUNET	M 13/063-2-C2

EXAMINER

HM22/0106

ROBERT P RAYMOND
BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY ROAD
P O BOX 368
RIDGEFIELD CT 06877

ART UNIT	PAPER NUMBER
1653	2

DATE MAILED: 01/06/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 30 DAYS ~~month(s)~~, or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1-99 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☑ Claim(s) 1-99 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claims 1, 6-39, 67-71, 75, 79, 96, drawn to compounds in which a = 0, b= 0 and Q = $-CH_2-$

2. Claims 1-66, 73, 74, 76, 77, 82, 86, 96 drawn to compounds in which a = 0, b= 0, and Q = -N-Y- .

3. Claims 1-11, 13-66, 73, 74, 76, 77, 80, 82, 88, 96 drawn to compounds in which one of "a" and "b" is 1, and the other of "a" and "b" is zero ("Q" can be either $-CH_2-$ or -N-Y-, if the claim at issue permits both possibilities).

4. Claims 1-7, 9-11, 13-66, 72-74, 76-78, 81-84, 87, 96, drawn to compounds in which both of "a" and "b" must be 1 ("Q" can be either $-CH_2-$ or -N-Y- if the claim at issue permits both possibilities).

5. Claims 89-92, drawn to a process of preparing compounds of Group 1.

6. Claims 89-92, drawn to a process of preparing compounds of Group 2.

7. Claims 89-92, drawn to a process of preparing compounds of Group 3.

8. Claims 89-92, drawn to a process of preparing compounds of Group 4.

9. Claims 97-98, drawn to a method of treating HCV infection by administering a compound of Group 1.

10. Claims 97-98, drawn to a method of treating HCV infection by administering a compound of Group 2.

11. Claims 97-98, drawn to a method of treating HCV infection by administering a compound of Group 3.

12. Claims 97-98, drawn to a method of treating HCV infection by administering a compound of Group 4.

13. Claim 99, drawn to a binary mixture which includes a compound of Group 1.

14. Claim 99, drawn to a binary mixture which includes a compound of Group 2.

15. Claim 99, drawn to a binary mixture which includes a compound of Group 3.

16. Claim 99, drawn to a binary mixture which includes a compound of Group 4.

Claims 93-95 have not been grouped. If these claims are amended to recite a method of use, or a compound in accordance with U.S. practice, the claims will be grouped accordingly.

The claimed inventions are distinct.

Claim 1, for example, has been sequestered into four groups:

(i) those compounds in which a = 0, b= 0 and Q = $-CH_2-$,

(ii) those compounds in which a = 0, b= 0 and Q = -N-Y- ,

(iii) those compounds in which one of "a" and "b" is 1, and the other of "a" and "b" is zero

(iv) those compounds in which both of "a" and "b" must be 1.

Group 1 compounds are acyldipeptides; there are only two amino acids in the molecule. Group 2 compounds are tripeptides, Group 3 compounds are tetrapeptides, and Group 4 compounds are pentapeptides. While it can perhaps be argued that there is little difference in a search for a 100-amino acid peptide as compared to a 99-amino acid peptide, the same cannot be said for very small peptides, where one single amino acid can make a dramatic difference in activity, and moreover, there is no specific name, such as insulin or

growth hormone, or fibroblast growth factor that is applied universally to di- and tripeptides. Different searches have to be conducted.

Inventions {1-4} and {9-12} are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). Inventions 5-8 and 1-4 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). Notwithstanding the foregoing, in the event that a group drawn to compounds (per se) is elected and found allowable, the claims drawn to a method of making or using the compounds will be rejoined for allowance, or at least further examination [*In re Ochiai* (**37** USPQ2d 1127)].

Inventions 13-16 and 1-4 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations. (M.P.E.P. § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because. The compounds can be used as such. However, in

the event that a group drawn to compounds (per se) is elected and found allowable, it is likely that claim 99 will be rejoined therewith.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

. . . .

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect a disclosed specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. A "specie" is a specific compound, with all substituent variables accounted for.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800